K013480

510(k) Summary

NOV 16 2001

SUBMITTER: COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004

CONTACT PERSON: Shawn Riedel
Phone: (303) 467-6521
Fax: (303) 467-6429

DATE PREPARED: October 18, 2001

DEVICE TRADE NAME: COBE SMARxT Optimin Surface Modified Hollow Fiber Membrane Oxygenator

COMMON/USUAL NAME: Hollow Fiber Membrane Blood Oxygenator with Integral Heat Exchanger

CLASSIFICATION NAME: Cardiopulmonary Bypass Oxygenator
Cardiopulmonary Bypass Heat Exchanger

PREDICATE DEVICE: COBE Optimin Hollow Fiber Membrane Oxygenator, #K991452

DEVICE DESCRIPTION/INDICATIONS FOR USE

The COBE SMARxT Optimin is a sterile device with non-pyrogenic fluid pathways, for single use only, and is not to be resterilized by the user. The device is a blood oxygenator with integral heat exchanger, intended to be used in surgical procedures requiring extracorporeal gas exchange support and blood temperature control, requiring a maximum blood flow rate of 5 liters/minute and lasting up to six hours. The size and specifications of the device make it particularly suited for smaller adult and pediatric patients.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE SMARxT Optimin Hollow Fiber Oxygenator is identical to the COBE Optimin Hollow Fiber Oxygenator in design, intended use, method of operation, components, packaging, and fundamental scientific technology. The primary difference between the two devices is that the COBE SMARxT Optimin Hollow Fiber Oxygenator contains a surface-modifying additive that improves the blood compatibility of the device.

TESTING TO DETERMINE SUBSTANTIAL EQUIVALENCE

In-vitro tests were performed to demonstrate that the COBE SMARxT Optimin Hollow Fiber Oxygenator described in this submission is substantially equivalent to the COBE Optimin Hollow Fiber Oxygenator (K991452).

CONFIDENTIAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2001

Mr. Shawn Riedel
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004

Re: K013480
COBE SMARxT Optimin Surface Modified Holow Fiber Membrane Oxygenator
Regulation Number: 804.4350, 870.4240
Regulation Name: Cardiopulmonary Bypass Oxygenator
Cardiopulmonary Bypass Heat Exchanger
Regulatory Class: II (Two)
Product Code: DTZ, DTR
Dated: October 18, 2001
Received: October 19, 2001

Dear Mr. Riedel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Indications For Use

510(k) Number (If known): K013480

Device Name: COBE® SMARxT® Optimin™ Hollow Fiber Membrane Oxygenator

Indications For Use:

The COBE® SMARxT® Optimin™ is indicated for use in surgical procedures requiring extracorporeal gas exchange support and blood temperature control. It is intended to be used in procedures requiring a maximum blood flow rate of 5 liters/min and lasting up to six hours.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013480

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)